SUMMARY STATEMENT

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Application Number: **1 R01 EB005724-01**

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Review Group: **BMIT**
Biomedical Imaging Technology Study Section

Meeting Date: **06/06/2005**
Council: **OCT 2005**
Requested Start: **12/01/2005**

RFA/PA: **PA04-158**
PCC: **AMRF**
Dual PCC: **3CCDPNB**
Dual IC(s): **AG**

Project Title: **Validation of Voxel-Wise Morphometries and Its Application to Alzheimer's Disease**

SRG Action: **Priority Score: 190 Percentile: 27.6**
Human Subjects: **10-No human subjects involved**
Animal Subjects: **10-No live vertebrate animals involved for competing appl.**

Project Year	Direct Costs Requested	Estimated Total Cost
1	125,000	174,982
2	125,000	174,982
3	125,000	174,982
TOTAL	375,000	524,947

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

NEW INVESTIGATOR

1R01EB005724-01 CHUNG, MOO

SCIENTIFIC REVIEW ADMINISTRATOR'S NOTES
NEW INVESTIGATOR

RESUME AND SUMMARY OF DISCUSSION: The applicants proposed to develop a morphometric analysis of the cortical surface and thickness in the MCI and AD population in order to more sensitively evaluate the dementia process. The Study Section concluded that the research builds on originally innovative ideas, that it addresses an important clinical problem and that the investigators are well qualified. The research was generally considered to be well planned and supported by some preliminary data. The written critiques outlined some weaknesses related to justification of multiple approaches, questions about the context of the synthetic database, use of the level-set, a possible flaw in longitudinal shape variation, an error in the mulit-scale, and in the definition of what is compatible. In discussion, the lack of an overall structure and the individual technical weaknesses were sufficient to reduce enthusiasm, offset somewhat by the potential clinical value of the research and the new investigator status of the applicant.

DESCRIPTION (provided by applicant): Although several studies in recent years have used voxel-wise morphometries such as voxel-based morphometry, deformation-based morphometry and tensor-based morphometry for characterizing the pattern of neuroanatomic changes in Alzheimer's disease (AD) progression, almost no study has performed a comparative analysis or a cross validation between different morphometric techniques. The implementation of these techniques varies from one study to another, so the extent of magnitude and location of structural changes are hard to compare quantitatively among studies that use different techniques. It is not even clear if two different methods will localize the structural changes in the same area of the brain. Further many researchers find it difficult to select the best morphometric framework for a given clinical population based on criteria other than simply having started out using one technique and becoming familiar with it. Each morphometric framework has a different approach to image preprocessing, the amount of image registration, selecting anatomical measures, choosing a statistical model and multiple comparisons for generating the final statistical parametric maps. We propose to formulate all these diverging morphometric techniques with many different choices of parameters in a single unified framework and perform a comparative analysis on both the Alzheimer's Disease Neuroimaging Initiative (ADNI) database and a well characterized synthetic data set where the ground truth is known. Different techniques with varying parameters will be compared and simultaneously validated in a multiscale fashion. The optimal scale, parameters and analysis framework will be identified. In addition, new thin-plate spline based cortical surface modeling that reduces the partial volume effect substantially will be developed. Based on the derived optimal parameters and framework, a host of anatomical measures will be correlated with the clinical status of subjects in the ADNI database. Given the.large amount of effort put into constructing the ADNI database and the importance of knowledge to be gained, it is vital for researchers to select the best morphometric framework and proper anatomical measures in understanding AD progression.

CRITIQUE 1:

Significance: Proposed is development of a morphometric analysis of the cortical surface and thickness in the MCI and AD population in order to more sensitively evaluate the dementia process. The approach taken is that of voxel-, deformation and tensor-based morphometries (VBM, DBM, TBM) and most recently, SBM, surface-based, using thin plate spline segmentation. The database available from the AD Neuroimaging Initiative will be used. The importance of this proposal lies in the need for sensitive and accurate measures of neurodegenerative decline.

Approach: The multiple approaches taken in this morphometric project, VBM, DBM, TBM, SBM with dementia raise several questions. The PI states (in the Specific Aims) that very few studies using these types of non-ROI morphometrics have demonstrated relationships with development of dementia. If so, how is that a combination of such studies would be expected to show sensitivity? More comparisons

may make significance testing more difficult. What advantages or disadvantages are being provided by these methods, e.g., the SBM relative to the TBM or other methods? The DBM, TBM (and SBM) approaches can be considered to be inter-related, and why one versus another (or a combination therein) is unclear. Furthermore given the localized process of dementia, certain regions (if analyzed in a given mode), will be more revealing than others in relation to their dementia. Given the numerous regions that can be analyzed, what will be the guidelines as to selecting the most important?

The value of the development of a synthetic database for consistent evaluation of these methods is excellent. However, when this is brought into context with real data, some significant problems remain. For example, how does the PI believe image signal to noise and contrast to noise, SNR and CNR, to differentially affect the various morphometric methods? It is likely, given that the images are pooled from a range of institutions, that the SNR and CNR may be categorically a feature of the data from a given site, rather than a random process.

As is well known, the most characteristic hallmark in early Alzheimers' dementia is that of memory loss. In this brain, this means that the hippocampus and amygdala are pathologically the earliest and most consistently involved portions of brain, with other associative cortices subsequently becoming involved. Thus in terms of analyzing the AD brain, the focus on hemispheric abnormalities is of interest for more advanced disease, but is likely to be less sensitive, and require more patients and images to detect an abnormality. However given that anatomical definition of the hippocampus remains at least in part a manual process, approaches to assessing the hippocampus and amygdala would be significantly important. The PI demonstrates collaborative preliminary data on this; it would be helpful to establish a specific path for evaluating limbic system structures.

Innovation: The PI has been working on the development of DBM, TBM and most recently has developed the thin plate spline (TPS) segmentation model which evaluates the tissue boundary. There are relatively few groups working on the issue of surface morphometric analysis.

Investigators: The PI is a relatively new investigator in the Department of Statistics at UW. He lists 10 publications of which 2 are in press and 2 are abstracts for conferences.

Environment: As the PI is primarily using data acquired at other institutions via the ADNI project, the emphasis at the environment at the University of Wisconsin is on the Biostatistics Department. The PI is a member of the Statistics and Biostatistics department, which has a strong record of methodologic development. The environment is excellent.

Overall Evaluation: This proposal is strong for development of a synthetic database for consistent comparison of morphometric approaches. However, there is little discussion as to the various advantages and disadvantages between the 4 analyses. The sensitivity to morphometric methods has been variable, and why for example the TBM may be more sensitive than DBM is not provided. The PI also does not discuss as how signal to noise, contrast to noise, and image artifact, which are not randomly distributed in the ADNI database may particularly differentially affect the several approaches.

Protection of Human Subjects from Research Risks: None, using de-identified data.

CRITIQUE 2:

Significance: Finding biomarkers for the detection of the early onset of Alzheimer's disease is highly significant. Using longitudinal imaging studies that quantify trends in structural changes as a result of Alzheimer's would be a moderately significant contribution. In addition, with the prevalence of diagnostic MRs throughout the world, the determination of a biomarker would be scalable to widespread healthcare. Performing a study to qualify and unify morphometric techniques for morphometric comparison was seen as highly significant and of considerable interest to the wider community. With the variability of morpohometric data available, investigating the most prominent

candidates within the context of the sensitivity and specificity with the most common measurement algorithms is also very significant. While the methods proposed (including the author's) are moderately novel, the encompassing study within synthetic data needs to be done and supported.

Approach: Prior to conducting extensive probing of the ADNI database with respect to the developed morphometry tools, a suite of image processing tools will be available to homogenize the data (e.g. intensity normalization, segmentation, registration, and templating). In accordance with the PI's desire to quantitatively validate all voxel-wise morphometry methods, a synthetic data set will be constructed which will incorporate shape, cortical surface, longitudinal, and intensity variation. Once completed, the a series of comparisons and hypotheses can be made and tested, respectively, across the different methods which include voxel-based, deformation-based, and tensor-based morphometry. This work will be followed by demonstration of the PI's method called thin-plate spline surface-based morphometry. The conclusion of the work will entail deployment to the ADNI database. Their statistical analysis methods will use a general linear model (which the PI has considerable experience with) which allows for ANOVA, MANOVA, ANCOVA, and MANCOVA. Given that anatomical change will be present over time, the PI has identified a means to factor out covariates such as age, gender, global cortical area differences, etc. Cross validation studies will also be performed with anatomical measures. Finally, the PI has plans to disseminate the methods and synthetic data to the wider scientific community.

With respect to some of the ideas regarding sulcal/gyri segmentation work, these are not particularly novel in that many have used similar parameters to characterize surfaces but for the purpose of shape tracking. In some sense, atrophy does represent a shape tracking problem. For example, the result that the sum of principal curvatures is an index for cortical bending is true but there is a more formal expression which involves the sum of the square of the curvatures. The more common expression represents the potential energy of a deformed idealized thin plate. One example of its use is in a paper by Pengcheng Shi et al. in TMI of 2000. While the PI is trying to use these with respect to sulci/gyri segmentation, similar questions have been forthcoming from shape tracking work which may be a valuable source for furthering development. On a related note, with respect to their cortical thickness measure, it is unclear that the evolving level-set can be used for correspondence. There is no data to support this claim. This is also confusing, if the level-set is to be used than one would expect very smooth cortical thickness maps. In this event, the heat kernel method would not be needed.

With respect to the simulation of synthetic data, the method for shape and cortical surface variation seems reasonable. However, the longitudinal shape variation seems flawed. The model is the same stochastic process. The process of longitudinal changes is much more correlated and systematic. This should not be modeled in the same manner as the other shape variation methods.

With respect to the multi-scale, the number of basis functions does not necessarily translate to more accuracy. It translates to larger degrees of freedom for registration. Ultimately, every method of image registration is limited in accuracy to the content, i.e. pattern, within the images.

With respect to hypothesis 2&3, what does "compatible" mean? How do you judge compatibility? Does this mean they should be within 1 standard deviation across multiple sets of data? More delineation of what constitutes "compatible" in the quantitative sense needs to be presented.

This proposal is well-laid out (although, the PI needs to use a spellcheck) and will add significant understanding to the performance of morphometric analysis. The PI has conducted a great deal of work in the various types of analysis and is well prepared to undertake this ambitious study of current methods as well as his own. While hypotheses are stated and many, many, quantities are to be calculated, the proposal does lack a cohesive study structure. It appears to be a collection of techniques and a collection of measurements. Based on this, it seems all possible perturbations will be performed. While potentially informative, the PI may be challenged to present the work in such a way that is clear to the wider scientific community.

Innovation: With respect to the individual methods and studies, there is limited innovativeness. However, the encompassing nature of the work is innovative. Identifying the predictive characteristics of different morphometric methods and then categorizing those methods with respect to their utility in a comprehensive analysis framework is innovative.

Investigators: Dr. Chung is a new investigator and is versed in the techniques required for this proposal. The background material is very thorough and it is evident that Dr. Chung has a good understanding of the field. Dr. Johnson and Dr. Alexander are good complements to the team with their experience with clinical data and AIR, respectively.

Environment: The overall environment seems exceptional. It was not clear exactly what resources are within Dr. Chung's control to conduct the work. However, based on the wealth of resources that are accessible by Dr. Chung, it is evident that the necessary tools are there. In addition, Dr. Johnson's PI status with University of Wisconsin site of the Alzheimer's Disease Neuroimaging Initiative is valuable for the future of this work.

Overall Evaluation: Overall, there is a great deal of enthusiasm for this proposal. In general, there was very high enthusiasm regarding the synthetic database to qualify different morphometric methods. With the PI offering his own versions of the VBM, DBM, TBM and his own TPS technique is excellent. The benchmark will be set by the PI himself with each of these techniques. This will encourage other investigators to put their versions of these algorithms to counteract those results. A great deal of enthusiasm was generated at enhancing this aspect of the proposal. The applicant is encouraged to look at the Vanderbilt Image Registration study as an example of something like this done previously. Offering up a synthetic data set which allows for direct comparable, controllable, and quantifiable results based on established methods is needed and exciting. To enhance this aspect further, the correlation of synthetic to realistic morphometric changes within the brain will be important. It was also suggested that it would be useful to be able to compare these methods with region of interest approaches as well. The simulated database is an ideal place to include such a comparison. With respect to ADNI studies, the perceived heterogeneity of the data to be analyzed diminished enthusiasm.

Protection of Human Subjects from Research Risks: Adequate.

Gender, Minority and Children Subjects: Adequate.

Animal Welfare: Non-applicable.

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

SCIENTIFIC REVIEW ADMINISTRATOR'S ADMINISTRATIVE NOTES:

The application claimed Exemption 4 for protection of human subjects because the proposed project will use existing anonymous, coded specimens and/or data without individual identifiers. According to the current 45 CFR Part 46, this no longer constitutes inclusion of human subjects, and the HHS human subjects regulations do not apply.

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

NOTICE: The NIH has modified its policy regarding the receipt of amended applications. Detailed information can be found by accessing the following URL address: http://grants.nih.gov/grants/policy/amendedapps.htm

NIH announced implementation of Modular Research Grants in the December 18, 1998 issue of the NIH Guide to Grants and Contracts. The main feature of this concept is that grant applications (R01, R03, R21, R15) will request direct costs in $25,000 modules, without budget detail for individual categories. Further information can be obtained from the Modular Grants Web site at http://grants.nih.gov/grants/funding/modular/modular.htm

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June 06, 2005 - June 07, 2005

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* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.